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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,952	12/24/2003	Jean-Louis Henri Dasseux	10173-111-999	9584

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EXAMINER
AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,952	DASSEUX ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-9,13-17,19 and 34-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,9,15,19 and 35-57* is/are rejected.

7)☒ Claim(s) *2,3,5,7,13,14,16,17 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. According to paper filed on Sep. 22, 2005, the applicants have canceled claims 4, 6, 10-12, 18 and 20-33 and furthermore, have amended claims 1, 2, 9, 15, 34 and 36-57.

2. Applicant's election of group I in paper filed on Sep. 22, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse; see MPEP 818.03(a).

3. Claims 1-3, 5, 7-9, 13-17, 19 and 34-57 are now pending in the application.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [120] as follows:

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the

application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an

application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 36-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating atherosclerosis, does not reasonably provide enablement for treating or preventing all other disorders mentioned in claims 36-57. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F.2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed: Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the

breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

The instant compounds are shown to reduce VLDL cholesterol, LDL cholesterol and increase HDL cholesterol. Based on these teachings, the instant compounds will have utility in treating disease conditions where high cholesterol levels are implicated in their etiology such as atherosclerosis. There is no teaching or guidance in the specification how the instant compounds having cholesterol lowering effect will have utility in treating and/or preventing every known cardiovascular disease, disorder of glucose metabolism, Alzheimer disease. Syndrome X, septicemia, thrombotic disorder, perooxisome proliferators activated receptor associated disorder, obesity, pancreatitis, hypertension, renal disease, cancer, inflammation, impotence, neurodegenerative diseases, metabolic syndrome disorders etc. There is no teaching in the prior art that compounds having cholesterol lowering effect are well known to have therapeutic utility in treating and/or preventing every known cardiovascular disease, disorder of glucose metabolism, Alzheimer disease. Syndrome X, septicemia, thrombotic disorder, perooxisome proliferators activated receptor associated disorder, obesity, pancreatitis, hypertension, renal disease, cancer, inflammation, impotence, neurodegenerative diseases, metabolic syndrome disorders etc. There are no working examples present showing efficacy of instant compounds in known animal models of every known cardiovascular disease, disorder of glucose metabolism, Alzheimer disease. Syndrome X, septicemia,

thrombotic disorder, perooxisome proliferators activated receptor associated disorder, obesity, pancreatitis, hypertension, renal disease, cancer, inflammation, impotence, neurodegenerative diseases, metabolic syndrome disorders etc. It is well known in the prior art that there are multiple mechanisms involved in the etiology of any disease condition and therefore, correcting only one mechanism will not prevent (completely cure) that disease condition. The instant compounds of formula 1 encompasses several hundreds of thousands of compounds based on the values of variables W1, W2, Z, G, m and x and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of every known cardiovascular disease, disorder of glucose metabolism, Alzheimer disease. Syndrome X, septicemia, thrombotic disorder, perooxisome proliferators activated receptor associated disorder, obesity, pancreatitis, hypertension, renal disease, cancer, inflammation, impotence, neurodegenerative diseases, metabolic syndrome disorders etc and hence their utility for treating these disorders.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 8, 9, 15, 19 and 35-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 9 and 15, the value of variable Y is defined as --- C(=)NH-CN--- is not consistent with the exemplified compounds. Although specification on pages 14, 16 and

18 defines this value as --- C(=)NH-CN--- yet according to the exemplified compounds (see compounds Ib 70, Ib 93, Ib 116 and Ib 129 on pages 47, 52, 57 and 59, respectively), as well as the parent application, this value should be ---C(=O)NH-CN----. An appropriate correction is required.

Claim 8 recites the limitation "(CH2)n for the value of variable Y" in claims 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 19 and 35 are directed to specific compounds. However, these compounds do not read upon the elected group of compounds of formula 1 of claim 1 since they lack two ketone groups.

In claims 36-57, the terms ----preventing or inhibiting ----- are indefinite since the degree of prevention or inhibition (such as 20%, 40%, 60%, 80% or 100%) is not defined and furthermore, how this prevention or inhibition is being assessed following in vivo administration of instant compounds?

In claim 36, the term ---cardiovascular disease---- is indefinite since specific diseases are not defined.

In claim 37, the term ---dyslipidemia --- is indefinite since it is not clear what types of lipids are elevated or reduced in a patient?

In claim 38, the term ---dyslipoproteinemia --- is indefinite since it is not clear what types of lipoproteins are elevated or reduced in a patient?

In claim 39, the term ---disorder of glucose metabolism---- is indefinite since specific disorders are not defined.

In claim 41, the term – syndrome X---- is indefinite since specific disorders are not defined.

In claim 43, the term – thrombotic disorder---- is indefinite since specific disorders are not defined.

In claim 44, the term – peroxisome proliferator activated receptor associated disorder---- is indefinite since specific disorders are not defined.

In claim 48, the term – renal disease---- is indefinite since specific diseases are not defined.

In claim 49, the term – cancer---- is indefinite since specific cancers are not defined.

In claim 50, the term – inflammation---- is indefinite since it is not clear what part of the body or tissue etc.is inflamed?

In claim 52, the term – neurodegenerative disease---- is indefinite since specific diseases are not defined.

In claims 53 and 54, the terms – fatty acid synthesis and sterol synthesis---- are indefinite since specific fatty acids and sterols are not defined and furthermore, what is the outcome of this inhibition? What is being treated?

In claim 55, the term –metabolic syndrome disorders---- is indefinite since specific disorders are not defined.

In claims 56 and 57, It is not clear which diseases are treatable by increasing HDL levels or lowering LDL levels since specific diseases are not defined.

Allowable Subject Matter

9. Claims 2, 3, 5, 7, 13, 14, 16, 17 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

C. S. Aulakh

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Art Unit 1625